

CLAIMS

- Sub B8*
1. A hydrogel comprising less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel,
 - 5 said hydrogel obtainable by combining acrylamide and methylene bis-acrylamide, radical initiation, and washing with pyrogen-free water or saline solution; said hydrogel being biocompatible, and said combining being in a molar ratio of 150:1 to 1000:1.
 - 10 2. A hydrogel comprising i) less than 3.5 % polyacrylamide by weight, based on the total weight of the hydrogel, cross-linked with methylene bis-acrylamide and ii) at least 95% pyrogen-free water or saline solution.
 3. A hydrogel for use as an injectable or implantable endoprosthesis said hydrogel
 - 15 comprising i) less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel, cross-linked with methylene bis-acrylamide and ii) at least 95% pyrogen-free water or saline solution.
 4. A hydrogel according to claim 1 further comprising at least 95% pyrogen-free water or
 - 20 saline solution.
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 5. A hydrogel according to claim 2, comprising at least 0.5%, such as at least 1 %, preferably at least 1.5% polyacrylamide, such as at least 1.6% polyacrylamide by weight, based on the total weight of the hydrogel.
 - 25 6. A hydrogel according to claim 2, characterised in that it has complex viscosity not less than 2 Pas, such as not less than 3, 4 or 5 Pas.
 7. A hydrogel according to claim 2, characterised in that it has complex viscosity from
 - 30 about 2 to 90, such as 5 to 80 Pas, preferably from about 6 to 76, such as from about 6 to 60, 6 to 40, 6 to 20, such as 6 to 15 Pas.

8. A hydrogel according to claim 2, characterised in that it has elasticity module of not less than 10 Pa, such as not less than 20, 25, 30, 31, 32, 33, 34 or 35 Pa, such as not less than 38 Pa.

9. A hydrogel according to claims 2, characterised in that it has elasticity module from about 10 to 700 Pa, such as about 35 to 480 Pa.

10. A hydrogel according to claim 2, characterised in that the cross-linked polyacrylamide is to such as degree so as to have an efficient cross-linking density of about 0.2 to 0.5%, preferably about 0.25 to 0.4%.

11. A hydrogel according to claim 1, wherein the molar ratio is from 175:1 to 800:1, such as from 225:1 to 600:1, preferably from 250:1 to 550:1, most preferably from 250:1 to 500:1.

12. A hydrogel according to claim 3, wherein the implantable endoprosthesis optionally comprises a silicone-based envelope housing the hydrogel.

13. An implantable or injectable endoprosthesis comprising a hydrogel as defined in claim 2.

14. An endoprosthesis according to claim 13, further comprising a silicone-based envelope housing the hydrogel.

15. An endoprosthesis according to claim 13 further comprising cells, such as stem cells, for cellular engraftment.

16. A method for the preparation of a hydrogel comprising the steps of combining acrylamide and methylene bis-acrylamide, radical initiation, and washing with pyrogen-free water so as to give less than 3.5% by weight polyacrylamide, based on the total weight of the polyacrylamide.

17. The method according to claim 16, wherein the hydrogel comprises at least 1.5% polyacrylamide, such as at least 1.6% polyacrylamide, by weight, based on the total weight of the hydrogel.

18. A method according to claim 16, wherein the washing step comprises swelling the product of the radical initiation step until the complex viscosity is from about 6 to 100 Pas.

5 19. The method according to claim 16, wherein the washing step comprises swelling the product of the radical initiation step until the elasticity module is from about 10 to 700 Pa from about 35 to 480 Pa.

20. The method according to claim 16, wherein the washing step comprises swelling the product for 50 to 250 hours, more typically for 70 to 200 hours.

21. The method according to claim 16, wherein the combining is in a ratio of acrylamide and methylene bis-acrylamide of about 150:1 to 1000:1.

15 22. The method according to claim 21, wherein the ratio of acrylamide to methylene bis-acrylamide is about 175:1 to 800:1, such as about 225:1 to 600:1, preferably about 250:1 to 550:1, most preferably about 250:1 to 500:1.

20 23. A method of treatment of a cosmetic or functional defect with an injectable or implantable biocompatible endoprosthesis comprising:
a) preparation of a polyacrylamide hydrogel, said polyacrylamide hydrogel comprising less than 3.5% by weight and said polyacrylamide being cross-linked using methylene bis-acrylamide,
b) injection or implantation a sufficient amount of said hydrogel into a region of the body
25 affected by a cosmetic or functional defect.

24. The method of treatment according to claim 23, wherein the polyacrylamide hydrogel comprises at least 0.5% polyacrylamide by weight, based on the total mass of the hydrogel, such as at least 1 %, such as at least 1.5%, such as at least 1.6 %
30 polyacrylamide by weight, based on the total mass of the hydrogel.

25. The method according to claim 23, wherein the preparation of the hydrogel is according to the method defined in claim 16.

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26. The method according to claim 23, wherein the endoprosthesis is for mammaplastic reconstruction or augmentation, treating reflux oesophagitis, body contouring, and penis enlargement.

5 27. The method according to claim 26, wherein the endoprosthesis for mammaplastic reconstruction or augmentation is injectable or implantable.

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10 28. The method according to claim 26, wherein the hydrogel comprises less than 1.6% polyacrylamide by weight, based on the total weight of the hydrogel, and wherein the endoprosthesis for mammaplastic reconstruction is implantable, said endoprosthesis optionally further comprising a silicone-based envelope.

15 29. The hydrogel according to claim 23, wherein the hydrogel comprises at least 1% by weight polyacrylamide, based on the total weight of the hydrogel.

30. A method of cosmetically altering a mammalian breast or of performing a partial or total mammaplastic reconstruction on a woman comprising implanting a polyacrylamide hydrogel endoprosthesis; wherein said hydrogel comprises more than 9.5% polyacrylamide by weight, based on the total weight of the hydrogel, and ii) at least 75% pyrogen-free water or saline solution.

20 31. The method according to claim 30, wherein the hydrogel comprises less than 25% by weight polyacrylamide, based on the total weight of the hydrogel, such as less than 20%.

25 32. The method according to claim 30, wherein the endoprosthesis further comprises a silicone-based envelope.

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30 33. A method of according to claim 23 comprising augmenting the size of a penis comprising the administration of a polyacrylamide hydrogel, wherein the hydrogel comprises less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel.

34. The method according to claim 33, wherein the hydrogel further comprises at least 95% pyrogen-free water or saline solution.

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35. The method according to claim 33, wherein the administration is by means of injection into cavernous tissue.

36. A method of augmenting the size of a penis comprising the implantation of a
5 polyacrylamide hydrogel endoprosthesis wherein the hydrogel comprises i) more than 9.5% polyacrylamide by weight, and ii) pyrogen-free water or saline solution.

37. The method according to claim 36, wherein the hydrogel has a complex viscosity of at
10 least 10 Pa.s, such as at least 15 Pa s, preferably at least 20 Pa s, more preferably at least 30 Pa s, most preferably at least 40 Pa s.

38. A method of cosmetically altering a mammalian body (body contouring) comprising
15 implanting a polyacrylamide hydrogel endoprosthesis, wherein the hydrogel comprises more than 9.5% polyacrylamide by weight, based on the total weight of the hydrogel, and ii) pyrogen-free water or saline solution.

39. A method for treating (reflux) oesophagitis comprising implanting or injecting a
20 polyacrylamide hydrogel endoprosthesis wherein the hydrogel comprises more than 6% polyacrylamide by weight, based on the total weight of the hydrogel.

40. The method according to claim 23 for treating (reflux) oesophagitis by implanting or
25 injecting an endoprosthesis wherein the hydrogel comprises less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel.

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